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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,224	06/04/2007	James Russell	RUSSELL4	7819
1444 7590 12/04/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SALMON, KATHERINE D	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 12/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Claims 1-10, 12-27, 40-48, and 52 are pending. Claims 11, 28-39, 49-51, and 53-55 have been cancelled.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 12-17, and 40-48, drawn to a method for making a prognosis in a subject of enhanced recovery from an inflammatory condition or increased risk of developing an inflammatory condition comprising determining a genotype defined by one or more polymorphic sites in the TLR-2 nucleic acid sequence.

Group II, claim(s) 18-21 and 52, drawn to a kit comprising a restriction enzyme, or a labeled oligonucleotide, and optionally instructions and an array.

Group III, claim(s) 22-27, drawn to a method of identifying subjects as being suitable for a trial that tests efficacy of a candidate drug comprising determine a genotype defined by one or more polymorphic sites in the TLR-2 sequence and sorting the subjects into a suitable and unsuitable group for said trial and a method for testing a candidate drug for its efficacy in the treatment of an inflammatory disease or condition comprising identifying subjects that are suitable for a trial and administering the candidate drug.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they lack the same or corresponding special technical features for the following reasons: According to PCT

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Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature is a polymorphism of a genotype defined by the TLR-2 nucleic acid sequence. Groups I-III do not share a special technical feature over the art because Lorenz et al. (Infection and Immunity Nov 2000 p. 6398) teaches polymorphism within the TLR02 gene associated with staphylococcal infection (abstract and Table 1). Therefore, the polymorphism of a genotype defined by the TLR-2 nucleic acid sequence fails to make a contribution over the prior art.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The species are in Group I and they include the list of inflammatory conditions included in Claim 14 and 17.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Claims 15 and 40-48 encompass species of inflammatory conditions.

The following claim(s) are generic: 1-10, 12-14, 16-17.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species lack the same or corresponding special technical feature because the species encompass the technical feature of a type of inflammatory condition. Lorenz et al. (Infection and Immunity Nov 2000 p. 6398) teaches polymorphism within the TLR02 gene associated with staphylococcal infection (abstract and Table 1). Therefore the technical feature of a type of inflammatory condition is taught by Lorenz et al.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement

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is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday - Friday 9AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon

/Sarae Bausch/

Primary Examiner, Art Unit 1634